

## REMARKS

Reconsideration of the above-referenced patent application is respectfully requested in view of the foregoing amendments and remarks set forth herein.

Claims 2-7 and 10 are pending herein. Claim 10 recites:

A method of producing a product for improving immune-function in mammals, comprising:

- a. selecting and culturing a strain of *Lactobacillus reuteri*,
- b. evaluating the cytotoxic activity of a substance derived from culturing the strain of *Lactobacillus reuteri*, the substance selected from the group consisting of cells of the strain of *Lactobacillus reuteri* and a supernatant obtained from growing the strain of *Lactobacillus reuteri* in suitable host cells, wherein a good toxin binding and neutralizing effect identifies a strain of *Lactobacillus reuteri* for further testing,
- c. providing cells of the identified strain of *Lactobacillus reuteri* of step b. to a test mammal,
- d. evaluating the immunomodulating activity of the identified strain of *Lactobacillus reuteri* of step b. in samples from the test mammal, wherein strain capability of increasing the number of CD4+ lymphocytes in the samples identifies a strain of *Lactobacillus reuteri* for use in the composition, and
- e. formulating the product to contain cells of the strain of *Lactobacillus reuteri* identified in step d.

Support for this terminology is found in original claim 1, and at paragraphs [0027] and [0041] and the examples of the published application.

In the Office Action of July 10, 2008, the Examiner took the following actions to which Applicant herein makes response: (1) rejected claims 1-7 under Section 112, second paragraph with respect to phrases such as "i.e..." and "e.g..." (claim 1, lines 4 and 6), and (2) rejected claims 1-7 under Section 102(b) as being anticipated or under Section 103(a) as being obvious over Cavadini et al. These rejections are traversed in application to the claims as amended, and consideration is requested of the patentability

of claims 1-7 now pending in the application.

**(1) Rejection of claims 1-7 under Section 112, second paragraph with respect to phrases such as “i.e...” and “e.g....” (claim 1, lines 4 and 6**

Claim 1 has been cancelled and replaced by new claim 10, which does not contain any such phrases. It is therefore submitted that the claims pending herein meet the requirements of Section 112, second paragraph.

**(2) Rejection of claims 1-7 under Section 102(b) as being anticipated or under Section 103(a) as being obvious over Cavadini et al.**

Applicant respectfully submits that Cavadini et al. neither teaches nor suggests the invention of claim 10 now pending herein. Cavadini et al. is for a pet food product containing probiotics, which of course are known for use in feeding many different types of animals. In contrast to the Examiner's statement that “the probiotic microorganism [of Cavadini] clearly possess immune-improving function and exhibit good neutralizing effects of toxic amine compounds which means that they have an inhibitory effect on toxin binding in the mammals”, Applicant's review of Cavadini et al. has found no indication that any or all of the microorganisms had any such characteristics (nor that Cavadini had any thought of using a selection method for such characteristics to produce a product, nor that an immune-improving function and neutralizing effects would yield an inhibitory effect on toxin binding in mammals). In fact, Cavadini seems to have contemplated use of a great diversity of microorganisms, including yeasts, moulds, and numerous species of bacteria, as evidenced by the extensive list of species usable in Cavadini et al.'s product (column 3, lines 3-30). The fact that there may previously have existed strains or species which had/have immunomodulating or cytotoxic or any other characteristic does not in any way in itself provide the information that such strains existed nor that one might use selection of a strain based on these characteristics to produce a product.

While strains that have the characteristics of strains selected according to Applicant's invention herein may have existed, there is no evidence, teaching or suggestion that such strains have ever been formulated into a product. There is a great diversity of microorganisms, and a great diversity within species of microorganisms.

Further, the immune systems consist of many types of proteins, cells, organs, and tissues, which interact in a very complex and dynamic network. Screening probiotics for potential use as immune-modulators is a laborious process and includes many items for consideration, the most important of which herein of course to select those bacteria that most effectively enhance the immune response. The efficacy of any Cavadini et al strain in improving the immune-function by the way disclosed in our invention has not been documented or disclosed. Characteristics ascribed to a probiotic strain are in general strain specific, and individual strains have to be tested for each property.

Applicant therefore respectfully submits that the method of claim 10, and the product of claims 2-7 produced with a strain with the characteristics of the strain of claim 10, is patentable under Section 102(b) and under Section 103(a) over Cavadini et al.

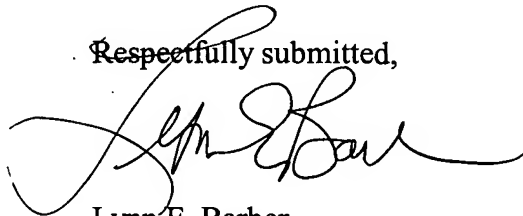
### **Conclusion**

For all the foregoing reasons, claims 2-7 and 10 are submitted to be fully patentably distinguished over the cited references and in allowable condition. Favorable consideration is therefore requested.

Applicant submits that no additional claims have been added and therefore that no fee is required for the presentation of this amendment except for the separately submitted fee for extension of time and the fee for the Request for Continued Examination. Any additional amounts that may be due for presentation of this amendment should be charged to Deposit Account No. 02-0825 of Applicant's attorney.

If any questions or issues remain, the resolution of which the Examiner feels would be advanced by a personal or telephonic conference with Applicant's attorney, the Examiner is invited to contact such attorney at the telephone number noted below.

Respectfully submitted,



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